DEC 1 3 2002 K023233

510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety and Effectiveness for the EBI® TargetCath™ Fluoro-Guided Steerable Catheter System is provided as required per Section 513(I)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** EBI, L.P.
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Jon Caparotta
Tel: (973) 299-9300, x3964

Date prepared: 9/26/2002

2. **Proprietary Name:** EBI® TargetCath™ Fluoro-Guided Steerable Catheter System
Common Name: Catheter
Classification Name: Catheter, Conduction, Anesthesia (868.5120)

3. **Predicate or legally marketed* devices that are substantially equivalent:**

EBI VueCath™ Spinal Endoscopic System – EBI, L.P.

Myelotec Video Guided Catheter – Myelotec, Inc.

Myelotec Myeloscope System – Myelotec, Inc.

Myelotec NaviCath™ Steerable Catheter – Myelotec, Inc.

NaviCath™ Steerable Catheter – Clarus Medical, LLC

NaviCath™ Steerable Catheter - Visionary™ BioMedical, Inc.

4. **Description of the device:** The EBI® TargetCath™ Fluoro-Guided Steerable Catheter System consists of several components and different accessories for delivery of approved epidural drugs. This system includes a disposable catheter, and various accessories.

5. **Intended Use:** When used with a fluoroscope, the EBI® TargetCath™ Fluoro-Guided Steerable Catheter can be used in the lumbar and sacral spine for observing epidural anatomy, pathology, and delivery of drugs approved for epidural indications.

6. **Materials:** The catheter is the patient contacting portion of the system. It is manufactured from medical grade polyurethane.

7. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the EBI® TargetCath™ Fluoro-Guided Steerable Catheter System and other spinal systems currently on the market. It is substantially equivalent* to the predicate device(s) in design, materials and intended use. Also, mechanical testing demonstrates that the device meets its functional requirements.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2002

EBI, L.P.
Jon Caparotta
Manager, Regulatory Affairs
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K023233
Trade/Device Name: EBI® TargetCath™ Fluoro-Guided Steerable Catheter System
Regulation Number: 868.5120
Regulation Name: Anesthesia conduction catheter
Regulatory Class: Class II
Product Code: BSO
Dated: September 26, 2002
Received: September 27, 2002

Dear Mr. Caparotta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K023233

Device Name: EBI® TargetCath™ Fluoro-Guided Steerable Catheter System

Indications For Use:

When used with a fluoroscope, the EBI® TargetCath™ Fluoro-Guided Steerable Catheter System can be used in the lumbar and sacral spine for delivery of drugs approved for epidural indications. The System may also be used for the purpose of assisting in the diagnosis and treatment of disease utilizing a caudal approach via the sacral hiatus.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023233